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10/643,589	08/18/2003	Debra D. Pittman	WYTH-P01-002	3988
28120 ROPES & GRA	7590 10/18/2007	EXAMINER		
PATENT DOC	KETING 39/41		ÉMCH, GREGORY S	
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			MAIL DATE	
			10/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary		Application No.	Applicant(s)		
		10/643,589	PITTMAN ET AL.		
		Examiner	Art Unit		
		Gregory S. Emch	1649		
The MAI Period for Reply	LING DATE of this communication app	ears on the cover sheet with the	correspondence address		
A SHORTENED WHICHEVER I Extensions of time after SIX (6) MONT If NO period for rep. Failure to reply with Any reply received	O STATUTORY PERIOD FOR REPLY S LONGER, FROM THE MAILING DA may be available under the provisions of 37 CFR 1.13 THS from the mailing date of this communication. Oly is specified above, the maximum statutory period whin the set or extended period for reply will, by statute, by the Office later than three months after the mailing adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATIO 36(a). In no event, however, may a reply be ting ATE OF THIS COMMUNICATION  ATE OF THIS COMUNICATION  ATE OF THIS COMMUNICATION  ATE OF THIS COMMUNICATION	N. mely filed the mailing date of this communication. ED (35 U.S.C. § 133).		
Status					
1) Respons	ive to communication(s) filed on <u>02 Ap</u>	oril 2007 and 23 July 2007.			
<i>,</i> —	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.				
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closed in	accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 4	53 O.G. 213.		
Disposition of Cla	ims				
4a) Of the 5) ☐ Claim(s) 6) ☑ Claim(s) 7) ☐ Claim(s)	1-71 and 83-92 is/are pending in the asteroid above claim(s) 32-41,45-71 and 83-8 is/are allowed.  1-31,42-44 and 88-92 is/are rejected. is/are objected to.  1-71 and 83-92 are subject to restriction	3 <u>7</u> is/are withdrawn from conside	eration.		
Application Paper	's				
10)⊡ The draw Applicant Replacem	ification is objected to by the Examine ing(s) filed on is/are: a) accember and a request that any objection to the content drawing sheet(s) including the correction declaration is objected to by the Ex	epted or b) objected to by the drawing(s) be held in abeyance. Se ion is required if the drawing(s) is ob	ee 37 CFR 1.85(a). pjected to. See 37 CFR 1.121(d).		
Priority under 35	U.S.C. § 119				
a)	dgment is made of a claim for foreign Some * c) None of: ertified copies of the priority documents ertified copies of the priority documents opies of the certified copies of the prior plication from the International Bureau tached detailed Office action for a list	s have been received. s have been received in Applica rity documents have been receiv u (PCT Rule 17.2(a)).	tion No red in this National Stage		
	erson's Patent Drawing Review (PTO-948) osure Statement(s) (PTO/SB/08)	4) Interview Summar Paper No(s)/Mail I 5) Notice of Informal 6) Other:	Date		

Art Unit: 1649

## **DETAILED ACTION**

### Election/Restrictions

Applicants' election with traverse of species c) SEQ ID NO: 7 in the reply filed on 23 July 2007 is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the election of species requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 32 and 85-87 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected subject matter, there being no allowable generic or linking claim.

### Response to Amendment

Claims 1, 3-7, 19, 20, 32, 42 and 44 have been amended and claims 72-82 have been canceled as requested in the amendment filed on 02 April 2007. Following the amendment, claims 1-71 and 83-92 are pending in the instant application.

Claims 33-41, 45-71, 83 and 84 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-31, 42-44 and 88-92 are under examination in the instant office action.

Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicants' response and withdrawn.

Art Unit: 1649

#### Information Disclosure Statement

A signed and initialed copy of the IDS paper filed 13 March 2007 is enclosed in this action.

## Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1, 2, 8-31 and 42-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants are directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. §112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001. Further, claims 3-7, and 88-92 are also subject to the instant rejection under 35 U.S.C. 112, first paragraph.

In the reply filed on 02 April 2007, Applicants assert that the specification sufficiently describes the claimed invention. Applicants assert, "One of skill in the art would know that the inventive portion of the claimed fusion proteins lies in the unique merging of technological features known in the art...the specification provides both working examples and sufficient description of the structural and functional

Art Unit: 1649

characteristics of the genus of the claimed fusion proteins." Applicants assert "that at the time this application was filed, TNF- $\alpha$  inhibitors, dimerizing polypeptides including amphiphilic polypeptides, purification polypeptides, stabilizing polypeptides, and targeting polypeptides were known and understood in the art." Applicants submit that they "have amended independent claims 1 and 20 to specify that the RAGE-LBE comprises an amino acid sequence at least 70% identical to an extracellular portion of SEQ ID NO: 7." Applicants further assert, "the specification provides at least two specific examples of RAGE-LBE, including a mouse RAGE-LBE (SEQ ID NO: 2) as shown in Figure 1B and a human RAGE-LBE (residues 1-344 of SEQ ID NO: 7) as shown in Figures 3A and 7. The mouse RAGE-LBE sequence (SEQ ID NO: 2) is about 77% identical to the human RAGE-LBE sequence (resides 1-344 of SEQ ID NO: 7) (see a sequence alignment enclosed as Exhibit A). The mouse RAGE-LBE is a functional homologous domain of the human RAGE-LBE as evidenced by its ability to bind to a RAGE ligand (see, e.g., Example 3 on pages 66-68; and Figure 6) and its ability to inhibit collagen-induced arthritis (see, e.g., Example 5 on pages 71-72; and Figure 4)."

Applicants' arguments have been fully considered and are not found persuasive.

As stated previously, the claims are genus claims because the specification (and claims) do not set forth the structure of the multitude of RAGE-LBE's, TNF-a inhibitors, dimerizing polypeptides including amphiphilic polypeptides, purification polypeptides, stabilizing polypeptides, and targeting polypeptides that are encompassed by the claims. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to

Page 5

Art Unit: 1649

be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. For some of the claims, there is not even identification of any particular portion of the structure that must be conserved. The fusion protein of claim 1, for example, requires that the RAGE-LBE comprises "an amino acid sequence at least 70% identical to an extracellular portion of SEQ ID NO: 7." This limitation encompasses as little as two amino acids that are 70% identical to the extracellular SEQ ID NO: 7. Further, there is no function recited by the majority of the claims and thus no structure/function correlation. Applicants disclose two working examples (i.e., a human RAGE-LBE fusion comprising residues 1-344 of SEQ ID NO: 7 and a mouse fusion protein comprising a RAGE-LBE that is 77% identical to the human RAGE-LBE sequence). A provision of two species is generally insufficient to satisfy the written description requirements of 35 U.S.C. 112, first paragraph. Moreover, although TNF inhibitors and dimerizing polypeptides are known in the art, given the vast number of these agents disclosed in the art, further guidance is needed for the skilled artisan to make and use the proteins and compositions that are actually functional. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought,

Art Unit: 1649

he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

With the exception of the full-length (or residues 1-344 of) SEQ ID NO: 7, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated fusion proteins comprising the amino acid sequence set forth in residues 1-344 of SEQ ID NO: 7 or comprising the amino acid sequence set forth in SEQ ID NO: 2, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicants are reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Art Unit: 1649

Applicants point to the Written Description guidelines, which include an example of a claim having written description which is directed to a protein and variants thereof that are at least 95% identical, with a specific catalytic function. Accordingly, the rejected claims are of a much larger scope than those deemed adequately described in the Written Description Guidelines.

The scope of enablement rejection of claims 1, 2, 8-31 and 42-44 under 35 U.S.C. 112, first paragraph, is maintained for reasons of record and as set forth below. Further, claims 3-7, and 88-92 are also subject to the instant rejection under 35 U.S.C. 112, first paragraph. The claims are rejected because the specification, while being enabling for RAGE-LBE fusion proteins comprising the amino acid sequence set forth in residues 1-344 of SEQ ID NO: 7 or comprising the amino acid sequence set forth in SEQ ID NO: 2, does not reasonably provide enablement for RAGE-LBE fusion proteins (and compositions thereof) comprising at least 70% homology with an extracellular portion of SEQ ID NO: 7 and also comprising any TNF- $\alpha$  inhibitor, any dimerizing polypeptide including any amphiphilic polypeptide, any purification polypeptide, any stabilizing polypeptide, or any targeting polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working

4040

Art Unit: 1649

examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988).

In the reply filed on 02 April 2007, Applicants submit, "As an initial matter, Applicants point out that the Examiner has mischaracterized the claimed invention. Applicants point out that the fusion protein of claim 1 or 20 does not comprise a  $\overline{\text{TNF-}\alpha}$ inhibitor. Instead, a TNF-a inhibitor is included in a pharmaceutical composition such as in claims 43-44" [Emphasis in original]. Applicants assert that the specification provides specific examples of RAGE-LBE fusion proteins (including those mentioned above) and that the specification provides a representative number of examples, thereby enabling the full scope of the claims. Applicants specifically state, "In sum, Applicants' working examples demonstrate how to make and use the RAGE-LBE fusion proteins. Therapeutic benefits of these RAGE-LBE fusion proteins are also disclosed. Further, the level of skill in the art was high at the time of the filing date of the present application. In fact, the techniques involved in the invention, all of which were well known in the art even before the filing date, are highly reliable and can be readily practiced by a skilled artisan. In view of the knowledge in the art and the ample teachings of the application, one of ordinary skill in the art would readily know how to make and use the claimed method in vivo, without undue experimentation" [Emphasis in original]. Further, in reply to the previous rejection under 35 U.S.C. 103(a), Applicants state, "It was well known in the art that recombinant proteins (e.g., the RAGE-LBE

Art Unit: 1649

<u>fusion proteins</u>) are <u>unpredictable</u> - they may not be biologically active due to improper tertiary and/or quaternary structure." [Emphasis added].

Applicants' arguments have been fully considered and are not found persuasive.

First, it is noted that the Examiner is well aware of the claimed invention and has not "mischaracterized" it. See p.4, of the previous office action, which states "Further, pharmaceutical compositions of the present invention include those that comprise a TNF- $\alpha$  inhibitor selected from the group consisting of a small molecule, an antibody, a peptidomimetic, and a TNFRII-Fc fusion protein (p.5, lines 14-20)" [Emphasis added]. Second, in response to Applicants statement "one of ordinary skill in the art would readily know how to make and use the claimed method in vivo", Applicants are reminded that the claims under examination are directed to product(s) and not to methods. As referred to previously, the claims require the use of several genera of polypeptides. Applicants have not described the common features of each genus such that the skilled artisan could identify individual members. The prior art fails to provide compensatory teaching; there are many examples of RAGE-LBE's, TNF-a inhibitors, dimerizing polypeptides, etc. Further, by Applicants' own admission, "it was well known in the art that recombinant proteins (e.g., the RAGE-LBE fusion proteins) are unpredictable - they may not be biologically active due to improper tertiary and/or quaternary structure." Moreover, the fusion protein of claim 1, for example, requires that the RAGE-LBE comprises "an amino acid sequence at least 70% identical to an extracellular portion of SEQ ID NO: 7." This limitation encompasses as little as two amino acids of SEQ ID NO: 7 since the claim encompasses "an extracellular portion" of

Art Unit: 1649

SEQ ID NO: 7. Thus, without further guidance it would require undue experimentation to practice the invention as broadly claimed.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. Due to the large quantity of experimentation necessary to make and use the fusion proteins comprising the plurality of amino acid sequences encompassed by the claims, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the claimed methods, and the breadth of the claims which encompass variant proteins, undue experimentation would be required of the skilled artisan to practice the invention as broadly claimed.

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.

Art Unit: 1649

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicants are advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 8-31 and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,864,018 to Morser et al. in view of Peppel et al. (J Exp Med. 1991 Dec 1;174(6):1483-9), further in view of U.S. 20020102604 to Milne Edwards et al. and as evidenced by WO 94/10308 to Spriggs et al.

The claims are directed to a fusion protein comprising a Receptor for Advanced Glycation End Product Ligand Binding Element (RAGE-LBE) and an immunoglobulin element, wherein the RAGE-LBE comprises an amino acid sequence at least 70% identical to an extracellular portion of SEQ ID NO: 7; further comprising a dimerizing polypeptide (including an amphiphilic polypeptide), a purification polypeptide, a

Art Unit: 1649

stabilizing polypeptide, or a targeting polypeptide, and associated protein complexes and pharmaceutical compositions that comprise a TNF-a inhibitor.

The '018 patent to Morser et al. discloses fusion proteins comprising RAGE polypeptides (including a polypeptide that is 84.6% identical to SEQ ID NO: 7; see attached sequence alignment A), and fragments, including but not limited to ligand binding elements, and immunoglobulin-like domains (col.7, line 45; col.8, lines 7-14; col.22, line 26-29), as in the instant claim 1. The '018 patent also teaches sRAGE (col.4, lines 65-66), as in claim 2. The patent discloses one or more amino acid substitutions, insertions, or deletions, i.e. point mutations, which cause altered specificity, enhanced potency, and higher affinity (col.8, line 43 - col.10, line 4), as in claim 11. Also, the patent teaches pharmaceutical compositions comprising the polypeptides of the invention and a pharmaceutically acceptable carrier (col.19, lines 21-24; col.20, lines 12-20), as in claim 19.

Upon reading the disclosure of the Morser et al. patent, the skilled artisan would have recognized the desirability of developing improved compositions for treating disorders that result from the association of AGEs and RAGE. Furthermore, the Peppel et reference teaches fusion proteins comprising soluble extracellular receptor moieties (of TNF-a) and immunoglobulin elements and teaches that these are effective inhibitors of the ligand-receptor interaction (entire document). Moreover, the '604 application teaches fusion proteins comprising polypeptides of the invention and functional fragments thereof (paragraphs 0117, 0176 and 0230). The reference also teaches antibodies (including IgG1, IgG2, IgG3, IgG4, IgA, IgD, IgE and IgM types) and

Art Unit: 1649

fragments thereof, (including heavy chains [VH], Fc domains and CH1 domains) as potential partners in the fusion proteins (para. 0364, 0376 and 0377), as in the instant claims 8-10 and 12-15. The '604 application teaches that the fusions can comprise any combination of the above-mentioned antibody fragments or domains (para. 0376 and 0377), as in claim 16. The '604 application teaches dimerizing polypeptides, including leucine zippers, as part of the fusions of the invention (para. 0312, 0313, 0314), as in claims 18-20, 27 and 31. Also, at paragraph 314, the '604 application states "examples of leucine zipper domains suitable for producing soluble multimeric proteins of the invention are those described in PCT application WO 94/10308, hereby incorporated by reference." Accordingly, the '308 document teaches jun and fos leucine zippers (p.1, line 34 – p.2, line 2), as in claims 28 and 29. The 604' application teaches stabilizing polypeptides (1260), targeting polypeptides (para. 1679), and purification polypeptides (para. 0176) as part of the fusion proteins of the invention, as in claim 20. The '604 reference also teaches amphiphilic polypeptides and fragments as part of the fusion proteins (para. 1679), as in claim 21, and teaches that fragments of polypeptides can at least 6, at least 8 to 10, 12, 15, 20, 25, 30, 35, 40, 50, 60, 75, 100, 125, 150, 175, 200, 225, 250, 275, 300, 350, 400, 450 or 500 amino acids (para. 0333), as in claims 22-25. The reference teaches a peptide helix bundle (para. 0671), as in claim 26 and teaches that formation of multimers (i.e., dimerization) can be the result of ionic interaction (i.e., oppositely charged polypeptides bound to each other; para. 0312), as in claim 30. The '604 document teaches protein complexes, comprising a protein of the invention (e.g., para. 0667), as in claim 42. The '604 document teaches TNF- $\alpha$  inhibitors (e.g.,

Art Unit: 1649

uromodulin) as part of pharmaceutical compositions of the invention (para. 0825), as in claims 43 and 44.

None of the cited references teach a fusion protein, wherein said immunoglobulin element comprises a CH1 domain of a first immunoglobulin class and a CH1 domain of a second immunoglobulin class, wherein the first and second immunoglobulin classes are not the same. However, in the instant case this is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal immunoglobulin composition of the fusion protein of claim 17 by varying the immunoglobulin type in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of immunoglobulin type would have been obvious at the time of Applicants' invention.

As evidenced by the prior art, the skilled artisan would have known that the interaction between AGE and RAGE is implication in numerous pathological disease states and that improved inhibitors of this interaction would be desirable. Thus, it would have been obvious to the person of ordinary skill to try to make and use the claimed fusion proteins and associated pharmaceutical compositions in an attempt to provide an improved method of treating RAGE associated disease. This is because the artisan has good reason to pursue the known options within his or her technical grasp.

Application/Control Number: 10/643,589 Page 15

Art Unit: 1649

In the reply filed on 02 April 2007 regarding the previous rejection under 35 U.S.C. 103(a), Applicants assert that Morser et al. do not teach or suggest an immunoglobulin element nor do they teach or suggest a dimerizing polypeptide, a purification polypeptide, a stabilizing polypeptide, or a targeting polypeptide. Further, Applicants assert that Milne Edwards et al. do not teach production of recombinant RAGE polypeptide(s) such as RAGE-LBE fusion proteins nor do they teach or suggest an association of the RAGE protein with any disease. Applicants allege that there is no common connection between these cited references and that there is no motivation for the skilled artisan to combine their teachings. Applicants further submit that there is no expectation of success, since "it was well known in the art that recombinant proteins (e.g., the RAGE-LBE fusion proteins) are unpredictable - they may not be biologically active due to improper tertiary and/or quaternary structure." Finally, Applicants cite case law that allegedly supports the view that "to render the claimed invention obvious, there must be a motivation to specifically combine Morser et al. and Milne Edwards et al. to arrive at the claimed invention."

Applicants' arguments have been fully considered and are not found persuasive.

First, Applicants' arguments concerning the separate references not disclosing portions of the claimed invention are irrelevant because "It is not necessary that the claimed invention be expressly suggested in any one or all of the references to justify combining their teachings; rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Regarding Applicants' arguments that there is

Art Unit: 1649

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no motivation or expectation of success to support the instant rejection under 35 U.S.C. 103 (a), it is noted that KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396) (available at <a href="http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf">http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf</a>). The rationale for the instant finding of obviousness is that the claims would have been obvious because a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

#### Conclusion

No claims are allowed.

Art Unit: 1649

# Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached 9:00 am - 5:30 pm EST (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory S. Emch/

Gregory S. Emch, Ph.D. Patent Examiner Art Unit 1649
11 October 2007

/<u>Elizabeth C. Kemmerer/</u> Primary Examiner, Art Unit 1646